REMARKS

This is a full and timely response to the Office Action mailed April 4, 2006, submitted concurrently with a Petition for a Two Month Extension of Time to extend the due date for response to September 4, 2006

By this Amendment, claim 4 has been amended to address the Examiner's objection to the claim. Support for the claim amendments can be found variously throughout the specification and the original claims. Thus, claims 1-4 and 7-15 are pending in this application, with claims 1-3 and 11-15 being withdrawn.

In view of these amendments, Applicant believes that the pending claims are in condition for allowance. Reexamination and reconsideration in light of the above amendments and the following remarks is respectfully requested.

Objection to the Claims

Claims 4 and 7-10 are objected to for a minor informality. Applicant has amended claim 4 to address the Examiner's objection to the claim. Thus, withdrawal of this objection is respectfully requested.

Objection under 35 U.S.C. §132

The amendment filed January 23, 2006 is objected to under 35 U.S.C. §132(a) since it allegedly introduces new matter into the disclosure. Applicant respectfully traverses this objection.

In support of their amendments to the specification, Applicant noted in the amendment filed January 23, 2006 that the insertion of the examples of mA116 scFv Ab into the specification does not constitute new matter since the disclosure of such antibodies are found in the reference, Alvi AZ, Hu WG, Fulton RE, Nagata LP, Coles JE, and Long MC: *Functional enhancement of a partially active single chain variable fragment antibody to Venezuelan equine encephalitis virus* Viral Immunology 2003; 16:213-222 (see page 2, lines 15-17, of the specification), which has been specifically incorporated by reference (see page 18, lines 1 and 2, of the specification).

The Examiner does not believe that the phrase "*the List of Prior Art Literatures referred to in the Background of the Invention section is incorporated by reference herein*"

provide proper support for the legal incorporation of the information described in the prior art literatures. Applicant respectfully disagrees with the Examiner in this regard.

As cited by the Examiner, §2163.07 of the Manual of Patent Examining Procedure allows for the incorporation of the content of another document or part thereof by reference to the document in the text of the specification. In other words, the information incorporated is as much a part of the application as filed as if the text was repeated in the application. Thus, replacing the identified material incorporated by reference with the actual text is not new matter.

What constitutes a proper incorporation by reference is defined by 37 C.F.R. §1.57(b) and (c) of the U.S. patent rules, portions of which are reproduced herein below for the Examiner's convenience.

> *(b) Except as provided in paragraph (a) of this section, an incorporation by reference must be set forth in the specification and must:*
>
> *(1) Express a clear intent to incorporate by reference by using the root words "incorporat(e)" and "reference" (e.g., "incorporate by reference"); and*
>
> *(2) Clearly identify the referenced patent, application, or publication.*
>
> *(c) "Essential material" may be incorporated by reference, but only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication, which patent or patent application publication does not itself incorporate such essential material by reference. "Essential material" is material that is necessary to:*
>
> *(1) Provide a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by the first paragraph of 35 U.S.C. 112;*
>
> *(2) Describe the claimed invention in terms that particularly point out and distinctly claim the invention as required by the second paragraph of 35 U.S.C. 112; or*
>
> *(3) Describe the structure, material, or acts that correspond to a claimed means or step for performing a specified function as required by the sixth paragraph of 35 U.S.C. 112.*

Applicant submit that the phrase "*the List of Prior Art Literatures referred to in the Background of the Invention section is incorporated by reference herein*" on page 18, lines 1 and 2, of the specification ***does provide*** proper support for the legal incorporation of the information described in the prior art literatures.

Applicant strongly believes that the phrase expresses a clear intent to incorporate by reference by using the root words "incorporated" and "reference" (i.e., "incorporated by reference herein"). Applicant disagrees with the Examiner's interpretation that the phrase only incorporates the list of references, not the *Alvi et al.* reference itself. There is no need to

incorporate the list of references since the list is already fully recited in the specification. It is clear that the intent of the phrase on page 18, lines 1 and 2, of the specification is to incorporate by reference the teachings contained in the listed references into the text of the specification. The list clearly identify the referenced publications as required by 37 C.F.R. §1.57(b)(2). Thus, the information contained in the listed references should be treated as part of the text of the application as filed and hence, the amendment to the specification filed January 23, 2006 should not be construed by the Examiner to be new matter under U.S. practice.

In addition, the Examiner argues that with regard to 37 C.F.R. §1.57(c), Applicant is attempting to incorporate essential materials by reference from a source other than a U.S. patent or U.S. patent Application publication since *Alvi et al.* is only a scientific journal publication. The Examiner believes that the monoclonal antibody mA116 is an essential material because they are required to provide a written description of the claimed invention. However, Applicant again respectfully disagrees with the Examiner in this regard.

Applicant clearly presents the citation and teachings of *Alvi et al.* in the Background of the Invention section. On page 6 of the specification, it is stated that "*[T]he present inventors have previously cloned and characterized several single-chain variable fragment antibodies (scFv Abs) against VEE (Alvi et al., 1999; Alvi et al., 2002; Alvi et al., 2003). Among them, **mA116 scFv Ab was well characterized**, showing sensitivity and specificity in recognition of VEE by immunoassay (Alvi et al., 2003).*" Applicant believes that such statements in the Background of the Invention section clearly demonstrate that the mA116 scFv Abs are deemed by the inventor to be non-essential material.

Further, Applicant would also like to note that most of these clones have already been disclosed in a U.S. Patent (i.e. U.S. Patent 6,818,748 "*Cloning, Expressions, Sequencing, and Functional Enhancement of Monoclonal ScFv Antibody against VEE*", issued 16 Nov 2004) which further indicates that the mA116 scFv Abs are deemed by the inventor to be non-essential material.

It should be noted that original claim 4, as originally presented, was directed to a fusion protein, SBP tagged scFv Ab, comprising a single-chain variable fragment antibody (scFv Ab) fused with a streptavidin-binding peptide (SBP) sequence. In other words, the scFv Ab was not limited to the mA116 scFv Ab, even though it was a preferred embodiment of the present invention.

Thus, for these reasons, withdrawal of this objection is respectfully requested.

Rejection under 35 U.S.C. §112

Claim 10 is rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Applicant respectfully traverses this rejection.

The Examiner has based this rejection on the position that the specification does not support the monoclonal antibody mA116 as a genus of antibodies. However, Applicant disagrees with the Examiner in this regard.

To satisfy the written description requirement under U.S. practice, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003). Here, in this case, Applicant believes that the claimed invention "*[A] fusion protein, SBP tagged scFv Ab, comprising a single-chain variable fragment antibody (scFv Ab) fused with a streptavidin-binding peptide (SBP) sequence, said fusion protein comprising (A) the amino acid sequence encoded by the nucleotide sequence shown in SEQ ID NO: 1 or (B) the amino acid sequence shown in SEQ ID NO: 2, wherein said scFv Ab is a mA116 scFv Ab*" is described in the specification and claims in sufficient detail **via words and structures** to establish that the inventor had possession of the claimed invention.

First, claim 4 defines the claimed fusion protein as *comprising (A) the amino acid sequence encoded by the nucleotide sequence shown in SEQ ID NO: 1 or (B) the amino acid sequence shown in SEQ ID NO: 2.* Further, claim 10 defines the scFv Ab as a mA116 scFv Ab which according to the description in the "Background of the Invention" section of the specification, is a ***well characterized*** scFv Ab against VEE based on previously known publications.

Thus, given the examples of mA116 scFv Abs and their respective Deposit Accession Numbers provided by the Applicants, and the teachings of the structures of the claimed fusion protein in the incorporated references, specification and claims, Applicant believes that they have clearly established possession of the claimed invention.

Applicant also wishes to note that the amendment to claim 10 was presented in the previously filed response to put the claim in better form under U.S. practice by introducing the proper article "*a*" before the newly introduce element of "*mA116 scFv Ab*".

With regard to the Examiner's indication that Alvi et al. does not provide support for the scFv mA116-6, Applicant wishes to direct the Examiner's attention to the teachings on page 216, last three lines of the first full paragraph, of Alvi et al. which disclose the scFv mA116-6.

Thus, for these reasons, withdrawal of this rejection is respectfully requested.

Request for Rejoinder

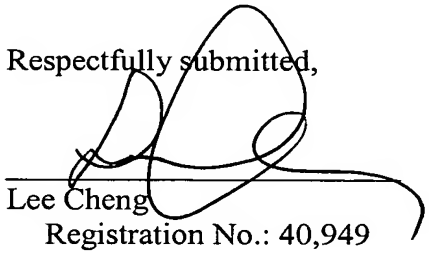
Applicant also hereby formally requests rejoinder of method claims 1-3 and 11-15 under *In re* Ochiai upon the allowance of the elected product claims. Applicant has previously amended non-elected claims 1 and 11 to depend on claim 4 to thereby include all the limitations of the allowable product claims in accordance with §821.04 of the MPEP.

CONCLUSION

For the foregoing reasons, all of the claims now pending in the present application are believed to be clearly patentable over the outstanding rejection. Accordingly, favorable reconsideration of the claims in light of the above remarks is courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the below-listed number.

Dated: August 30, 2006

Respectfully submitted,



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